



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,775	09/15/2003	Andrea Marinello	930071-2001	2185
20/999 7590 08/21/2009 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
1611				
MAIL DATE		DELIVERY MODE		
08/21/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/662,775

Applicant(s)

MARINELLO ET AL.

Examiner

Isis A. Ghali

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The finality of the office action mailed 11/13/2008 is hereby withdrawn.

Claims 1-33 are pending

Claims 1-12 and 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/06/2006.

Claims 13-30 are included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is confusing as it recites that the face mask covers the upper part of the head. Claim 13 recites that the mask covers the nose and mouth which constitute the lower part of the head, and claim 21 that depends on claim 13

Art Unit: 1611

recites the opposite, the mask covers the upper part of the head, which would be the eyes and forehead. Claim 21 appears to be improperly depends on claim 13.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1611

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 13-14, 17-19, 21-26, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello (GB 2088714, IDS filed 03/15/2004), Ludwin et al. (US 2,262,711, recited in 892 form submitted 12/26/2006), and Smaldone (US 6,748,949, currently recited on 892 form).

Applicant Claims

Applicants' claims 13 is directed to a device comprising a facial mask accommodated to allow unobstructed respirator⁷ function of the nostrils and the mouth, an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person in need thereof. Claim 25 is directed to a method of treating sinusitis comprising the step of securing the said device to a person's head.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Marinello teaches using revulsive to treat sinusitis, wherein the preferred revulsive is mustard applied to the skin overlying the sinuses impregnated into a

Art Unit: 1611

compress and pressed there-against by means of elastic inflatable cushion (page 5, lines 11-20). Mustard contains mustard oil, which is allyl isothiocyanate (page 3, lines 95-96). Marinello teaches impregnation of absorbent dressing (compress) with measured amount of the revulsive, applying the dressing to cutaneous surface at point overlying the inflamed organ, and exerting pressure on the dressing using inflatable elastic pad applied as near as possible to the external skin surface overlying the point of inflammation. The pressure produces the following effects: (1) squeezing the dressing and releasing the revulsive, (2) widening of the pores of the skin subjected to pressure, and (3) penetration of the revulsive through the widened pores near the inflamed area. See page 3, lines 7-55. Marinello teaches that the compression of the revulsive to the site of application allows the revulsive to enter the dilated pores of the skin and causes reaction in the deep blood vessels of the body underlying the skin to which the revulsive is applied (page 2, lines 110-115). Marinello teaches avoidance of contact of the compress with the eye (page 5, lines 20-21).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although Marinello teaches treating of sinusitis and desired avoidance of eye contact, however, Marinello does not explicitly teach the use of face mask as instantly claimed by claims 13 and 25.

Ludwin teaches medical nebulizer used for treating sinusitis (col.1, lines 1-5). The nebulizer comprises face mask, medicament in a chamber, and pressure provided

Art Unit: 1611

to vaporize the medicine (col.1, lines 13-39). The medicaments are contained in a sponge member and applied under pressure (col.2, lines 9-12; col.3, lines 21-23). The pressure under the mask provides efficient delivery of the vaporized drugs and allows penetration of the drug into small pores of the sinus tracts (col.1, lines 36-39).

Ludwin does not explicitly teach that the face mask is unobstructive and covers the nose and mouth.

Smdalone teaches face mask for delivering pressurized drugs from nebulizer wherein the mask comprises features that reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes. The mask covers the mouth and nose and has openings (unobstructed) to release the undesired drug. The mask eliminates discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. See col.5, lines 3-53; Figures 3-5, 7, 11, 13; col.7, lines 6-13, 18-22; col.15, lines 10-22. The mask having holes, therefore is unobstructive as required by claims 13 and 25, and adapted to allow respiration as required by claim 23. The face mask is made of flexible thermoplastic materials as required by claim 24 (col.7, lines 34-36). The figures show that the face mask covers the lower part of the head as required by claim 22.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

At the time of the invention it was known to treat sinusitis by administering dressing impregnated with mustard oil to the skin overlying sinuses and using means of

inflatable elastic pad to squeeze the revulsive agent from the compress to the skin as taught by Marinello. Avoidance of eye irritation was also desired.

Further, delivering medicaments to the sinuses using impregnated dressing and face mask using pressure force was known in the art at the time of the invention as taught by Ludwin.

Additionally, at the time of the invention it was known to use nebulizer to deliver drugs under pressure using masks that cover the nose and mouth that have openings to release the pressure to avoid eye irritation as taught by Smaldone.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses as taught by Marinello, and further use a face mask to cover the impregnated compress as taught by Ludwin. One would have been motivated to do so because Ludwin teaches that sinuses can be treated using face mask and applying pressure under the mask will provide efficient delivery of the vaporized drugs and allow penetration of the drug into small pores of the sinus tracts. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask to help penetration of the vaporized drug into the pores of sinus tracts to ensure efficient drug delivery to the sinuses.

Additionally, one having ordinary skill in the art at the time of the invention would have been motivated to replace the mask taught by Ludwin with the mask that covers the nose and mouth and has openings as taught by Smaldone. One would have been motivated to do so because Smaldone teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask covering the mouth and the nose and having holes wherein the mask is comfortable and eliminates irritation of the eye.

Regarding claim 21 that recites wherein the mask covers an upper part of the face, applicants failed to show unexpected results obtained if the mask cover the upper part of the head.

Regarding claim 19 that recites using rubber pump to inflate the inflatable pad, the prior art recognized applying pressure to deliver mustard from the impregnated compress. Applicants failed to show unexpected results obtained from using the rubber pump to provide pressure over the means used by the prior art to create pressure.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

Art Unit: 1611

instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

7. Claims 15, 16, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello with Ludwin and Smaldone, and further in view of the article by Depree et al. (Flavour pharmaceutical properties of the volatile sulphur compounds of Wasabi), currently provided.

The combined teachings of Marinello with Ludwin and Smaldone are previously discussed as set forth in this office action.

Although Marinello teaches solution of the mustard oil, page 3, line 28, however, the reference does not explicitly teach water and its temperature to activate the revulsive agent as instantly claimed by claims 15, 16, 27 and 28.

Depree teaches that isothiocyanates that is present in mustard oil have the property of decomposition in water and their decomposition in water is temperature dependent; it is more rapidly at 37° C than at 0° C (page 333, left column, first paragraph).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard oil solution impregnated into a compress and use an inflatable elastic cushion and pressurized face mask covering the mouth and the nose and having holes as taught by the combined teachings of Marinello with Ludwin and Smaldone, and further use solution of mustard in water at a temperature between 37° C and above 0° C as taught by Depree. One would have been

motivated to do so because Depree teaches that isothiocyanates that is present in mustard have the property of decomposition in water and their decomposition in water is temperature dependent, and decomposition occurs more rapidly at 37° C than at 0° C. One would reasonably expect to treat sinusitis using mustard oil solution in water impregnated into a compress and using an inflatable elastic cushion and pressurized face mask wherein the mustard is provided in water at a temperature between 37° C and above 0° C to ensure solubility of the active agent in the solution.

Therefore, the temperature currently claimed falls within that known and taught by the prior art. It has been held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.

See MPEP 2144.05 [R-5].

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

8. Claims 20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello with Ludwin and Smaldone, and further in view of the Bracken (US 5,429,126, current 892 form).

The combined teachings of Marinello with Ludwin and Smaldone are previously discussed as set forth in this office action.

Although Ludwin and Smaldone teach face masks, however, the references do not explicitly teach means for securing the mask to the head as instantly claimed by claims 20 and 29.

Bracken teaches respiratory mask that is secure, comfortable and snug fit to head while permitting increased mobility during a course of treatment to enable a person to attach and remove the respiratory mask with ease and to remove and reinsert the elastic strap repeatedly without constant damage and frequent replacement (col.1, lines 53-60; figures).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard oil solution impregnated into a compress and using an inflatable elastic cushion and pressurized face mask covering the mouth and the nose and having holes as taught by the combined teachings of Marinello with Ludwin and Smaldone, and further use mask having elastic strips to secure the mask of the head of user as taught by Bracken. One would have been motivated to do so because Bracken teaches that such a mask with elastic strips is secure, comfortable and snug fit to head while permitting increased mobility during a course of treatment to enable a person to attach and remove the respiratory mask with ease and to remove and reinsert the elastic strap repeatedly without constant damage and frequent replacement. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion and pressurized face mask having securing elastic strips to secure the mask to the user

head wherein the mask is secure, comfortable, snug fit to the user's head and further permits mobility and repeated use of the mask.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Art Unit: 1611

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG